



DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS



18 APR 2017

MEMORANDUM FOR SGVT

ATTN: MAJ CARRIE LITKE-WAGER

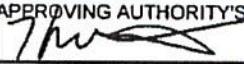
FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled A Randomized Trial to Measure the Efficacy of Applying Task-Oriented Role Assignment to Improve Neonatal Resuscitation presented at/published to Pediatric Academic Society, San Francisco, CA, 6-9 May 2017 in accordance with MDWI 41-108, has been approved and assigned local file #17186.
2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are a 59 MDW staff member, we can forward your request for funds to the designated Wing POC at the Chief Scientist's Office, Ms. Alice Houy, office phone: 210-292-8029; email address: alice.houy.civ@mail.mil.
4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.


LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol) Litke-Wager, Carrie, Major, O-4, SGVT	3 GME/GHSE STUDENT <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	4. PROTOCOL NUMBER C.2015.099d
5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.) A Randomized Trial to Measure the Efficacy of Applying Task-Oriented Role Assignment to Improve Neonatal Resuscitation			
6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED: A Randomized Trial to Measure the Efficacy of Applying Task-Oriented Role Assignment to Improve Neonatal Resuscitation			
7. FUNDING RECEIVED FOR THIS STUDY? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO FUNDING SOURCE:			
8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
9. IS THIS MATERIAL CLASSIFIED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.			
11. MATERIAL IS FOR: <input checked="" type="checkbox"/> DOMESTIC RELEASE <input type="checkbox"/> FOREIGN RELEASE CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED			
<input type="checkbox"/> 11a. PUBLICATION/JOURNAL (List intended publication/journal.)			
<input type="checkbox"/> 11b. PUBLISHED ABSTRACT (List intended journal.)			
<input checked="" type="checkbox"/> 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting) Pediatric Academic Society, San Francisco, CA, 6-9 May 2017			
<input type="checkbox"/> 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meeting)			
<input type="checkbox"/> 11e. OTHER (Describe: name of meeting, city, state, and date of meeting)			
12. HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO ASSIGNED FILE # 17052 DATE March 15, 2017			
13. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC)			
DATE April 07, 2017			
14. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email) Litke-Wager, Carrie Ann, R, carrie.a.litke-wager.mil@mail.mil		15. DUTY PHONE/PAGER NUMBER 210-916-7078	
16. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript			
LAST NAME, FIRST NAME AND M.I. a. Primary/Corresponding Author Litke-Wager, Carrie	GRADE/RANK O-4/Major	SQUADRON/GROUP/OFFICE SYMBOL 959/CSPS/59MDW/SGVT	INSTITUTION (If not 59 MDW)
b. Mu, Thornton	O-5/LTC	MCHE-ZDP-N	SAMMC
c. Delaney, Heather	O-4/MAJ	MCHE-ZDP-N	SAMMC
d.			
e.			
17. IS A 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDW 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.			
18. AUTHOR'S PRINTED NAME, RANK, GRADE Litke-Wager, Carrie Ann, Major, O-4		19. AUTHOR'S SIGNATURE 	20. DATE March 30, 2017
21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE Mu, Thornton, LTC, Neonatology Fellowship Program Director		22. APPROVING AUTHORITY'S SIGNATURE 	23. DATE March 30, 2017

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS		
1st ENDORSEMENT (59 MDW/SGVU Use Only)		
TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	24. DATE RECEIVED 9 April 2017	25. ASSIGNED PROCESSING REQUEST FILE NUMBER 17186
26. DATE REVIEWED 10 Apr 2017	27. DATE FORWARDED TO 502 ISG/JAC	
28. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES If yes, give date. _____ <input type="checkbox"/> N/A		
29. COMMENTS <input checked="" type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED The abstract is approved.		
30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Rocky Calcote, PhD, Clinical Research Administrator	31. REVIEWER SIGNATURE CALCOTE.ROCKY.D.11782 45844	32. DATE Digitally signed by CALCOTE.ROCKY.D.1178245844 DN: c=US, ou=US Government, ou=DOD, ou=PKI, ou=USAF, ou=USAFA, cn=CALCOTE.ROCKY.D.1178245844 Date: 2017.04.10 07:03:36 -05'00'
2nd ENDORSEMENT (502 ISG/JAC Use Only)		
33. DATE RECEIVED	34. DATE FORWARDED TO 59 MDW/PA	
35. COMMENTS <input type="checkbox"/> APPROVED (in compliance with security and policy review directives) <input type="checkbox"/> DISAPPROVED		
36. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	37. REVIEWER SIGNATURE	38. DATE
3rd ENDORSEMENT (59 MDW/PA Use Only)		
39. DATE RECEIVED April 11, 2017	40. DATE FORWARDED TO 59 MDW/SGVU April 11, 2017	
41. COMMENTS <input checked="" type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED Please add disclaimer to your presentation. "The Views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components" Once added, presentation is approved and cleared for public release by Public Affairs.		
42. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Kevin Inuma, SSgt/E-5, 59 MDW Public Affairs	43. REVIEWER SIGNATURE INUMA.KEVIN.MITSUG U.1296227613	44. DATE Digitally signed by INUMA.KEVIN.MITSUG U.1296227613 DN: c=US, ou=US Government, ou=DOD, ou=PKI, ou=USAF, ou=USAFA, cn=INUMA.KEVIN.MITSUG U.1296227613 Date: 2017.04.11 16:28:41 -05'00'
4th ENDORSEMENT (59 MDW/SGVU Use Only)		
45. DATE RECEIVED	46. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> COULD NOT BE REACHED <input type="checkbox"/> LEFT MESSAGE	
47. COMMENTS <input type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED		
48. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	49. REVIEWER SIGNATURE	50. DATE

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

1. The author must complete page two of this form:
 - a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M), SG5 R&D, Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH, Congressionally Directed Medical Research Program (CDMRP); Grants; etc.]
 - b. In Section 2, there may be funding available for journal costs. If your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.
2. Print your name, rank/rank, sign and date the form in the author's signature block or use an electronic signature.
3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box
4. Attach a copy of your abstract, paper, poster and other supporting documentation.
5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.
6. On page 2, have either your unit commander, program director or immediate supervisor:
 - a. Print their name, rank/rank, title, sign and date the form in the approving authority's signature block or use an electronic signature.
7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). This should be accomplished no later than 30 days before final clearance is required to publish/present your materials. If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.
8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.
9. Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. Note: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.
10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DTIC). See 59 MDW 41-108, *Presentation and Publication of Medical and Technical Papers*, for additional information.
11. The Joint Ethics Regulation (JER) DoD 5500.07-R, *Standards of Conduct*, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review. To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to obtain all approvals for the event.

If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation should have an ethics review.

If your travel is being paid for (in whole or in part) by a non-Federal entity (someone other than the government), a legal ethics review is needed. These requests for legal review should come through the 59 MDW Gifts and Grants Office to 502 ISG/JAC.

If you are receiving an honorarium or payment for speaking, a legal ethics review is required.

If you (as the author) or your supervisor check "YES" in block 17 of the Form 3039, your research or technical documents will be forwarded simultaneously to the 502 ISG/JAC legal office and PAO for review to help reduce turn-around time. If you have any questions regarding legal reviews, please contact the legal office at (210) 671-5795/3365, DSN 473.

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:

"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:

"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401_IP :

"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

A Randomized Trial to Measure the Efficacy of Applying Task-Oriented Role Assignment to Improve Neonatal Resuscitation

Despite receiving Neonatal Resuscitation Program (NRP) training, providers still fail to comply with NRP guidelines during neonatal resuscitation. In an effort to address performance gaps we devised a teaching paradigm, called 'Task-Oriented Role Assignment', in which we have delegated a specific set of tasks to be performed within the traditional role assignments used during NRP. We hypothesize this method will improve communication and task delegation, thereby improving NRP performance.

Health care professionals taking the NRP course were randomized to either the control group, which received NRP only, or the study group, which received NRP and training with 'Task-Oriented Role Assignment'. This paradigm consists of 5 roles: team leader, cardiac chief, airway chief, line/medication chief, and recorder, with each role containing a subset of pre-determined tasks. The mnemonic, 'B CALMR', is incorporated into a visual aid to help learners remember the role assignments. Subjects participated in standardized NRP simulations which were video recorded and evaluated for task completion and team behaviors by two independent, blinded investigators. Participants rated their ability to perform NRP before and after receiving NRP training. A sample size of 72 is needed to detect a difference of 0.8 standard deviations.

We have enrolled 65 subjects (31 study, 34 control). Both groups rated themselves similarly in all categories of NRP performance except communication, where the control group had higher ratings both before (mean = 3.1control, 2.5study; p = 0.045) and after NRP (mean = 4.2control, 3.7study; p = 0.020). 11 simulations, performed by 12 participants have been evaluated. The control group had better team behavior scores in several components, such as leadership (mean = 4 control, 3 study; p = 0.03). However, both groups scored similarly in overall NRP task performance with mean scores of 73.7% and 74.5% for the control and study groups (p = 0.74, 95% CI -5.7-4.2). Evaluation of the recorded simulations is on-going.

Regardless of group assignment, participants perceived their ability to perform NRP to be greater after receiving any NRP education, as evident by higher post-course self-assessment scores. At this time, the use of Task-Oriented Role Assignment does not appear to improve team behavior or technical performance during neonatal resuscitation. However, our sample size is small, and more numbers are needed to draw conclusions.

Disclaimer: The views expressed are those of the author(s)/presenter(s) and do not reflect the official views or policy of the Department of Defense or its Components.



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
REGIONAL HEALTH COMMAND CENTRAL (PROVISIONAL)
4070 STANLEY ROAD, SUITE 121
JBSA FORT SAM HOUSTON, TEXAS 78234-2715

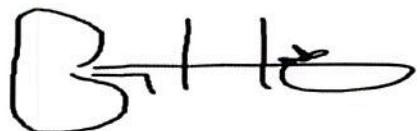
MCSR-CS

15 June 2016

MEMORANDUM FOR: Maj Carrie Litke-Wager, MD
FROM: Brooke Army Medical Center Institutional Review Board
PROJECT TITLE: A Randomized Trial to Measure the Efficacy of Applying Task-Oriented Role Assignment to Improve Neonatal Resuscitation
REFERENCE #: C.2015.099d
SUBMISSION TYPE: Continuing Review/Progress Report
ACTION: APPROVED
IRB APPROVAL DATE: 15 June 2016
EXPIRATION DATE: 16 June 2017
REVIEW TYPE: Expedited
PROJECT STATUS: Active, Open to Enrollment

1. Congratulations! The Brooke Army Medical Center (BAMC) Institutional Review Board (IRB) reviewed and APPROVED continuation of your aforementioned protocol and supporting documents. The research continues to be judged Minimal Risk. Your protocol and continuing review application was reviewed for regulatory compliance under Expedited Review, in accordance with 32CFR219.110 (b)(1) Federal Register Categories 6 and 7. Applicable OHRP (under 45CFR46), FDA (under 21CFR50 and 56) and HIPAA (45CFR160 and 164) regulations were also consulted, as appropriate.
2. The following minor changes in research were also requested and approved in accordance with 32CFR§219.110(b)(2).
 - P01 removed Dr Ward as statistician. Respective changes now reflected in P01 Version 2, 13 June 2016.
3. This protocol will automatically expire on June 16, 2017. If you plan to continue beyond this date, the required continuing review progress report is due to the BAMC IRB no later than six (6) weeks prior to expiration. Please Note: If a Data Safety and Monitoring Board (DSMB) has been named, please submit its most recent report with your annual Continuing Review. The IRB will attempt to assist you by sending a reminder; however, submission of the continuing review report is your responsibility. Failure to submit the report on time will result in the expiration of your protocol and a requirement to cease all research activities until the protocol can be reapproved.

4. If at any time you have questions regarding your responsibilities as a Principal Investigator, please do not hesitate to contact Amy Holstein at 210-916-8227 or amy.l.holstein.civ@mail.mil. On behalf of the entire IRB, we wish you much success with your research protocol. We look forward to reviewing the progress of your study in the coming months.

A handwritten signature in black ink, appearing to read "Amy L. Holstein".

AMY L. HOLSTEIN
RN, MPH, CCRP, CIP
Designated Expedited Review IRB Member